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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,491	07/01/2003	Vahid Saadat	USGINZ02112	3557
40518 7590 04/15/2008 LEVINE BAGADE HAN LLP 2483 EAST BAYSHORE ROAD, SUITE 100 PALO ALTO, CA 94303				
EXAMINER				
YABUT, DIANE D				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/612,491

Applicant(s)

SAADAT ET AL.

Examiner

DIANE YABUT

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9, 16, 26, 27 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 16, 26, 27 and 32-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendment received on 11/15/2007.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-7, 9, 26-27, and 32-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Koike et al.** (U.S. Patent No. **6,056,760**) in view of **Gannoe et al.** (U.S. Patent No. **6,746,460**), **Laufer et al.** (U.S. Pub. No. **20040194790**), and **Saadat** (U.S. Patent No. **7,186,262**).

Claims 1, 6, 7, and 38: Koike et al. discloses providing a delivery catheter 1 having a needle 2, or piercing element, translatably disposed therein, a distal end, one or more anchors 4 disposed within the needle, and sutures T₁ and T₂ coupled to the anchors, advancing the delivery catheter and needle through the a first tissue wall and then through a second tissue wall, and ejecting a first anchor from a distal tip of the needle on a first side of the first tissue wall and ejecting a second anchor from the needle on a second side of the second tissue wall (Figures 6-10). Koike discloses the anchor having a suture T₁ attached thereto, withdrawing the needle from the tissue wall whereby the suture is extended

through the tissue wall (Figures 7-8). Koike et al. discloses the claimed invention except for a stabilization device disposed at the distal end, engaging the stabilization device to a tissue wall of the gastrointestinal lumen before advancing the catheter through the tissue wall, advancing the delivery catheter and needle into the gastrointestinal lumen, or tract of a patient, and translating a fastener over the suture whereby a tension force is created on the suture and said tissue fold is maintained.

Gannoe et al. teaches delivering the delivery catheter and needle, or tissue piercing element into the gastrointestinal lumen, or tract of a patient in order to reduce the amount of food desired by patients who may be obese (col. 1, lines 12-30 and 52-67). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue piercing element into the gastrointestinal lumen, as taught by Gannoe et al., to Koike et al. in order to aid obese patients in managing the amount of food desired and eaten.

Laufer et al. teaches a stabilization device **740** disposed at the distal end, engaging the stabilization device to a tissue wall of the gastrointestinal lumen before advancing the catheter through the tissue wall (Figure 4A and page 3, paragraphs 79 and 83). It would have been obvious to one of ordinary skill in the art to provide a stabilization device that engages with the a GI tissue, as taught by Laufer et al., to Koike et al. since it was known in the art that tissue piercing elements may injure or tear tissue from translating or puncturing, as well as withdrawing, retracting movement if the tissue is not stabilized and a stabilization device may prevent injury to the tissue.

Saadat teaches translating a fastener **532** comprising a collar with a central channel through which a suture **506** extends whereby a tension force is created on the suture and said tissue fold is maintained (Figure 49A; col. 24, lines 42-51). Since Koike et al. discloses that the suture threads **T1** and **T2** are ligated together by a knot (Figure 10), it would have been obvious to one of ordinary skill in the art to modify Koike et al. by replacing the knot with a fastener or crimp, as taught by Saadat, so that the tension is maintained and the fastener may be translated over the suture after the tissue has been approximated to adjust tension.

Claims 26, 32, and 35: Koike et al. discloses the claimed invention, including withdrawing the piercing element from the catheter through tissue and using a connection element in tying together suture threads **T₁** and **T₂** and a first and second anchor, said second anchor being connected to said first anchor by a suture and withdrawing the needle from the tissue fold whereby the suture is extended through the tissue fold (see explanation for Claims 1, 6, 7, and 38 above), except for engaging and pulling a tissue wall of the gastrointestinal lumen to create a tissue fold, holding the tissue fold within the patient, moving the first and second anchors on either side of the tissue fold, maintaining the tissue fold via the anchor and the suture and a connection element, and translating a fastener over the suture.

Gannoe et al. teaches engaging and pulling a tissue wall of the gastrointestinal lumen to create a tissue fold, holding the tissue fold within the patient, moving anchors on either side of the tissue fold, and maintaining the

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tissue fold via the anchor and the suture and a connection element (Figure 4A). It would have been obvious to one of ordinary skill in the art to provide the step of creating a tissue fold, as taught by Gannoe et al., to Koike et al., since it was known in the art that obesity may be treated by forming folds in the gastrointestinal lumen which aids obese patients in managing the amount of food desired and eaten.

As mentioned above in discussion of Claims 1, 6, 7, and 38, Saadat teaches advancing a fastener over a suture to apply a tension force on said suture, and it would have been obvious to one of ordinary skill in the art to modify Koike et al. by replacing the knot with a fastener or crimp so that the tension is maintained and fastener that may be translated over the suture after tissue has been approximated to adjust tension, as taught by Saadat.

Claim 3: Koike et al. discloses ejecting an anchor from a distal tip of the needle comprising translating a push rod **3** disposed in the needle (Figure 1 and col. 4, lines 58-67).

Claims 4 and 9: Koike et al. and Gannoe et al. disclose the claimed invention except for the stabilization device comprising a coil **740**, or tissue holding element, having a sharpened tip and engaging the stabilization device to the tissue wall comprising rotating the coil to engage the coil into the tissue wall before advancing the catheter through the first tissue wall. See explanation for Claims 1, 6, 7, and 38.

Claim 5: Koike et al. discloses advancing the needle through the tissue wall further comprising translating the needle distally through the delivery catheter (Figures 6-10).

Claim 27: Koike et al. discloses the claimed invention except for providing a second anchor including a suture coupled thereto and creating a second tissue fold on an opposing tissue wall.

Gannoe et al. teaches providing a second anchor including a suture coupled thereto and creating a second tissue fold on an opposing tissue wall (Figure 5A and col. 5, lines 23-37). It would have been obvious to one of ordinary skill in the art to provide a second tissue fold, as taught by Gannoe et al., to Koike et al. since it was known in the art that multiple folds greatly reduces the area of a gastrointestinal lumen, and again, aids obese patients in managing the amount of food desired and eaten.

Claims 33, 34, 36, and 37: Koike et al. discloses the claimed invention except for forming the tissue fold, or bringing the first and second tissue walls adjacent, results in reducing the cross sectional area of a lumen in a patient, as well as the volume of an organ.

Gannoe et al. teaches forming the tissue fold, or bringing the first and second tissue walls adjacent, results in reducing the cross sectional area of a lumen in a patient, as well as the volume of an organ. See explanations for Claims 1, 6, 7, 26, 27, 32, 35, and 38.

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3. Claims 2 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Koike et al.** (U.S. Patent No. **6,056,760**), **Gannoe et al.** (U.S. Patent No. **6,746,460**) and **Laufer et al.** (U.S. Pub. No. **20040194790**), as applied to Claims 1 and 6 above, and further in view of **Matsui et al.** (U.S. Patent No. **6,352,503**).

Claims 2 and 16: Koike et al., Gannoe et al., and Laufer et al. discloses the claimed invention except for an imaging element in the vicinity of the distal end of the delivery catheter and using the imaging element to provide visual guidance during engagement of the stabilization device to the tissue wall.

Matsui et al. teaches an imaging element **1** in the vicinity of the distal end of the delivery catheter and using the imaging element to provide visual guidance during engagement of the stabilization device to the tissue wall (col. 5, lines 18-30). Matsui et al. teaches that the use of an endoscope can readily and positively perform treatment on a body cavity of a patient (col. 1, lines 47-51 and col. 2, lines 1-16). It would have been obvious to one of ordinary skill in the art to provide an imaging element, as taught by Matsui et al., to Koike et al., Gannoe et al., and Laufer et al. in order to perform treatment on a body cavity readily and positively perform surgery on a body cavity.

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4. Claims 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr. et al., hereinafter "**McGuckin**" (U.S. Patent No. **6,835,199**) in view of **Adams et al.** (U.S. Patent No. **6,736,828**).

Claims 39-40: McGuckin discloses moving a catheter **10** into a patient, holding a tissue fold **T** within the patient with a tissue grasper **30**, and extending a piercing element **16** from the catheter through the tissue fold (Figures 21-22).

Although McGuckin acknowledges that the piercing element may be a stapling apparatus or a tissue approximating structure, McGuckin does not expressly disclose using first and second anchors on first and second sides, respectively, of the tissue fold to approximate the tissue.

Adams et al. teaches moving a first anchor **42** out from a piercing element **40**, on a first side **46** of a tissue fold, withdrawing the piercing element from the tissue fold, moving a second anchor (opposite end of **42**) out from the piercing element, on a second side **44** of the tissue fold, and holding the tissue fold via a connection element connecting the first and second anchors (Figures 5-7). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of McGuckin by adding first and second anchors on either side of the tissue fold, as taught by Adams et al., since it was well known in the art to use anchors which have an increased area over which the forces of securing the tissue will be distributed (col. 6, lines 25-36).

Response to Arguments

5. Applicant's arguments filed 11/15/2007 have been fully considered but they are not persuasive.

The applicant generally argues that the varied subject matter contained in the references relied upon by the examiner is indicative of the nonobviousness of the claims at issue. For instance, the device of Koike would not be physically compatible with the devices of Gannoe or Laufer, and therefore one of ordinary skill in the art would not have combined the above references. However, the test for obviousness is not whether the features of the secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

Regarding the combination of Koike and Gannoe: Both inventions are directed towards approximation of tissue, and it would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue piercing element into the gastrointestinal lumen, as taught by Gannoe, to Koike in order to aid obese patients in managing the amount of food desired and eaten.

Regarding the combination of Koike and Laufer: Both inventions are directed towards piercing of tissue, and it would have been obvious to one of ordinary skill in the art to provide a stabilization device that engages with the GI tissue, as taught by Laufer, to Koike since it was known in the art that tissue piercing elements may injure or tear tissue from translating or puncturing, as well

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as withdrawing, retracting movement if the tissue is not stabilized and a stabilization device may prevent injury to the tissue.

Regarding the combination of Koike and Saadat: Both inventions are directed towards tissue fasteners. It would have been obvious to one of ordinary skill in the art to modify Koike et al. by replacing the knot with a fastener or crimp, as taught by Saadat, so that the tension is maintained and the fastener may be translated over the suture after the tissue has been approximated to adjust tension.

Regarding the combination of Koike, Gannoe, Laufer, and Matsui: It would have been obvious to one of ordinary skill in the art to provide an imaging element, as taught by Matsui, to Koike, Gannoe, and Laufer in order to perform treatment on a body cavity readily and positively perform surgery on a body cavity.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731